

**REMARKS**

The present application provides an improved method for preparing a transformed cotton plant which uses petioles as an explant for producing callus tissue. The method of the present application significantly enhances the efficiency of the transformation and shortens the time required to produce a transformed, regenerated plants.

Claims 1 to 18 are pending in the application. In this response claims 1, 9 and 11 are amended to better define what applicants regard as their invention. Claim 15 is canceled and new claim 19 is submitted. The dependency of claims 16 and 17 are also amended.

The objections to claims 2-18 made in the previous office action because of informalities have been withdrawn.

The rejection of claims 1-18 under 35 USC § 112, second paragraph has also been withdrawn.

Although not indicated in the outstanding office action, it appears that claims 9 and 18 are not presently rejected and should be allowable if rewritten in independent form.

**Rejections Under 35 U.S.C. § 102(b)**

Claims 1-6 and 15-17 are rejected under 35 USC §102(b) as being anticipated by Strickland (WO 97/12512). Applicants maintain that the method of Strickland does not anticipate the method of the present application as Strickland does not provide an

enabled method for producing transformed cotton plants using petioles as explants. It is asserted in the office action that the lack of an enabling disclosure in Strickland would not preclude anticipation of claim 1-6 and 10-17, in view of the decisions In re Hafner, 161 USPQ 783 (CCPA 1969) and In re Schoenwald, 22 USPQ2d 1671 (Fed. Cir. 1992).

Applicants respectfully disagree. A patent claim "cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." Elan Pharmaceuticals v. Mayo Foundation for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003). "The disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter. It is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation." Id. at 1055.

In Hafner, the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." (Emphasis added.) Thus, Hafner's earlier filed, issued German patent was determined to be 102(b) prior art to a continuation-in-part application containing further statements of how to use the compound that was fully disclosed in the German patent. The court reasoned that the patent provided a disclosure sufficient to anticipate the continuation-

in-part application, even though it did not meet the how to use requirement of section 112, first paragraph. The court reasoned that the requirement of section 112 that the specification teach how to use, as well as how to make the disclosed invention was an additional requirement for patentability not found in section 102(b). In Hafner, there was no dispute as to whether the specification taught how to make the fully disclosed compound produced by a fully disclosed process.

Similarly in in re Schoenwald, the court found that a claim directed to a compound disclosed in a prior art publication was anticipated even though the publication did not disclose a use for the compound. The discovery of a use for the compound by the alleged inventor did not make the compound new. As the court explained "paramount among the patentability requirements is that that which is sought to be patented must be new." In re Schoenwald at 1672. Thus, both decisions relate to whether the how to use requirement of section 112 is met, not whether the prior art reference is adequate to enable possession of the desired subject matter.

The method for producing a transformed cotton plant using callus from explants of petioles of the present application is new. While Strickland may have wished that his method would work for tissues of different explants, and thus included a statement regarding transformation of different plant tissues in his application, the unpredictability of the field of cotton transformation at the time the Strickland application was published (and first filed) raised significant doubts as to whether the Strickland method would work with tissues other than the specific hypocotyl tissue exemplified in the application.

Moreover, the invention of the present application is not taught by Strickland. Strickland asserts, but provides no evidence to show, that his method for transforming cotton, which uses media having no plant hormones, can be used to transform callus derived from tissues other than the hypocotyls specifically disclosed in the application. During prosecution of the US application corresponding to the cited Strickland publication, the examiner found that the application was not enabled for plant tissues other than the hypocotyl tissue specifically exemplified. As the examiner asserted, "cotton has traditionally been recalcitrant to tissue culture and somatic embryogenesis." (See Paper No. 6, Office Action from application no. 08/539,176, at 5, a copy of which is attached to this response.) The examiner further asserted that "choice of explant type may inhibit the ability of cultured cotton explants to develop into embryogenic callus." Id. Thus, he concluded that given the unpredictability inherent in the process, the breadth of the claims and the lack of guidance in specification, undue experimentation would have been required by one skilled in the art to evaluate the ability of a multitude of non-exemplified cotton explants of produce embryogenic callus on hormone-free callus initiation medium. Id. at 6. Thus, Strickland limited his claims to a method using only hypocotyl explants. (The examiner also determined that Strickland was free of the prior art based on the unpredictability of that art. Id. at 6.)

The Strickland publication does not anticipate the claims of the present application because it did not put the public in possession of the method for producing a transgenic cotton plant using petioles as explants disclosed in the present application.

The cases cited in the outstanding office action, In re Hafner and In re Schoenwald, were decided based on facts that are distinguishable from those of the present case. In contrast to the issue decided there, Strickland does not fully disclose either a transformed cotton plant produced using petioles as an explant or a process that would demonstrate to one of skill in the art that a transformed plant could be produced using petioles as explants for callus tissue. Just as the examiner of Strickland's U.S. application found, undue experimentation would have been required to modify the method of Strickland to achieve the result achieved by the method disclosed and exemplified in the present application.

#### **Rejections Under 35 USC § 103(a)**

Claims 1-8 and 10-17 are rejected under 35 USC §103(a) as being unpatentable over Strickland (WO 97/12512) in view of Finer (1988, Plant Cell Reports 7:399-402.) Applicants again respectfully traverse this rejection.

As discussed above, Strickland does not put the public in possession of a method of producing a transgenic cotton plant made using callus from a petiole explant. As the examiner of the Strickland U.S. application corresponding to WO 97/12512 found, it would have required undue experimentation to evaluate the method of Strickland using explants from other tissue sources given the unpredictability of the art of cotton transformation. Moreover, the method of the present application, as presently claimed, uses low concentrations of plant hormones in the medium used to prepare

callus from petiole explants. Strickland teaches that the medium of this step should be hormone-free.

Finer is cited as disclosing the use of medium having glutamine as a nitrogen source for embryoid formation in a report of plant regeneration from somatic embryogenic suspension cultures of cotton. The reference is further cited as disclosing the use of a medium for establishing suspension cultures from callus containing 0.1 mg/l 2,4-dichlorophenoxyacetic acid. For proliferation of the embryogenic suspension 5 mg/l of 2,4-dichlorophenoxyacetic was used. (See the abstract of Finer.)

To establish a *prima facie* case of obviousness, the cited prior art references must disclose or at least suggest to one of ordinary skill in the art each element of the claimed invention. Strickland taken in view of Finer does not teach or even suggest the method of the present claims.

As asserted above, Strickland does not provide a method for producing transgenic cotton plants using petioles as explants. Strickland's disclosure of cotton tissues other than the hypocotyl tissue in his limited examples is nothing more than an expression of a hope that the disclosed method may work with other explant tissues. It is not an invention known or used by others as it does not enable possession of a method of transforming cotton callus tissue derived from a petiole explant. See Elan, 346 F. 3d at 1055.

Finer does not provide further disclosure to overcome the deficiencies of the Strickland. Finer discloses a method for plant regeneration from somatic embryogenic

suspension cultures of cotton initiated from cotyledonary tissues. Nothing in Finer suggests a method for producing a transformed cotton plant, nor does it suggest that low concentrations of plant hormones such as those used in the present application can be used to provide an efficient method for producing callus from petiole tissues during and following incubation with *Agrobacterium*. In fact, Finer teaches that the concentration of 2,4-dichlorophenoxyacetic acid in medium should be increased ten fold for proliferation of the embryogenic suspension.

Neither Strickland or Finer set forth or even suggest the invention of the present application. Strickland teaches a method for generating embryogenic callus from a cotton hypocotyl tissue explant that is cultivated on cotton initiation medium having no exogenous plant hormones. This disclosure actually teaches away from the regeneration methods of Finer which rely on the presence of plant hormone to produce embryogenic callus from cotyledonary tissues. Strickland asserts that "the conducive nature of hormone-free regeneration also means that cotton plant tissues which have not been commonly utilized for regeneration can be now be used to produce somatic embryos." WO 97/12512 at page 11, lines 7-10. Thus, the cited references, when considered together, provide contradictory teachings. They do not provide the motivation to combine the use of petioles as a source for callus in medium having low concentrations of plant hormones in a more efficient procedure for producing a transformed cotton plant. A person of ordinary skill in the art at the time the invention


was made would have recognized that the claimed method for preparing a transgenic cotton plant using petioles as explants for callus tissue was an advance in the art.

Applicants respectively assert that a rejection under 35 USC § 103(a) over Strickland in view of Finer, as it may be applied to present claims 1-14 and 16-19, would be in error and respectively ask that the rejection be withdrawn.

### **Conclusions**

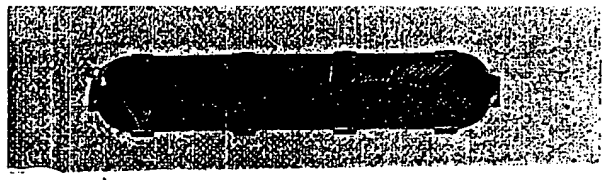
Applicants believe the present claims 1-14 and 16-19 are in condition for allowance and respectfully request a timely notice to that effect. Should additional issues arise that can be effectively dealt with by a timely discussion with Applicants' representative, the Examiner is respectfully asked to contact the undersigned so that this case can be quickly passed to issue.

Respectfully submitted,

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08 539176	435-1723	Class	Subclass	ISSUE CLASSIFICATION
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JM

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UTILITY SERIAL NUMBER 08 539176	PATENT DATE DEC 0 8 1998	PATENT NUMBER
SERIAL NUMBER 08/539,176	FILING DATE 10/04/95	CLASS 800
	435	172.3
		GROUP ART UNIT 111
		EXAMINER FOX

STEVEN G. STRICKLAND, DAVIS, CA.

APPLICANTS  
\*\*CONTINUING DATA\*\*\*\*\*  
VERIFIED

DXF

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\*\*FOREIGN/PCT APPLICATIONS\*\*\*\*\*  
VERIFIED

none DXF

Issue Fee

FOREIGN FILING LICENSE GRANTED 04/25/96

Foreign priority claimed 35 USC 119 conditions met	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	AS FILED	STATE OR COUNTRY CA	SHEETS DRWGS. 2	TOTAL CLAIMS 16	INDEP. CLAIMS 2	FILING FEE RECEIVED \$830.00	ATTORNEY'S DOCKET NO. CGNE-117
Verified and Acknowledged	Examiner's Initials							

ADDRESS  
CALGENE INC  
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DAVIS CA 95616

TITLE  
COTTON TRANSFORMATION

U.S. DEPT. OF COMM./PAT. & TM—PTO-436L (Rev.12-84)

PARTS OF APPLICATION FILED SEPARATELY		Applications Examiner	
NOTICE OF ALLOWANCE MAILED		CLAIMS ALLOWED	
3-11-98		Total Claims 10	Print Claim 1
ISSUE FEE 72		DRAWING	
Amount Due 1320.00	Date Paid 4/21/98	Sheets Drwg. 2	Figs. Drwg. 2
Label Area		ISSUE BATCH NUMBER B42	
		PREPARED FOR ISSUE	
<p>DAVID T. FOX PRIMARY EXAMINER GROUP 1649</p> <p>David T. Fox Primary Examiner</p> <p>WARNING: The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 368. Possession outside the U.S. Patent &amp; Trademark Office is restricted to authorized employees and contractors only.</p>			



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/539,176	10/04/95	STRICKLAND	S CGNE-117

EXAMINER

18M2/0107

CALGENE INC  
1920 FIFTH STREET  
DAVIS CA 95616

ENV. 2

ART UNIT

PAPER NUMBER

1803

DATE MAILED: 01/07/97

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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☒ Responsive to preliminary communication(s) filed on 12/17/96.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- ☒ Claim(s) 1-16 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-16 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The drawing(s) filed on 10/4/95 is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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The declaration is objected to for its claiming priority to application Serial No. 07/440,987, which is directed to completely different subject matter. It is noted that another commonly owned application filed on 1 August 1991, with the same last three digits of the serial number recited in the declaration, is directed to methods for cotton regeneration and transformation. However, that application has no common inventor with the instant application. In addition, that application is completely silent with respect to the use of hormone-free callus initiation medium or the use of explants from seeds or immature seedlings. Accordingly, the effective filing date of the instant application is deemed to be its actual filing date of 4 October 1995. Applicant is requested to submit a substitute declaration which omits reference to the incorrect "parent" application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 9-11, drawn to methods of regenerating cotton plants, classified in class 435, subclass 240.5, for example.
- II. Claims 1, 4-8 and 12-16, drawn to methods of transforming cotton plants, classified in class 435, subclass 172.3, for example.

Claim 1 will be examined to the extent that it reads on the elected invention.

The inventions are distinct, each from the other because:

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The inventions of each group involve physiologically and biochemically divergent products and processes not required by the other group. The invention of Group II involves plant transformation techniques, bacterial strains, and foreign genes not required by the invention of Group I. The invention of Group I can be practiced with untransformed cotton tissue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter and fields of search, as evidenced by their divergent classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Carl Schwedler on 19 November 1996 a provisional election was made with traverse to prosecute the invention of Group II, claims 1, 4-8 and 12-16. Affirmation of this election must be made by applicant in responding to this Office action. Claims 2-3 and 9-11 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

On 17 December 1996, Carl Schwedler submitted a preliminary amendment (paper no. 5) which changed the dependency of claims 2-3 and 9-11 so that they depended upon either claim 4 or claim 7, which were part of Group II. The preliminary amendment also included an election of Group II without traverse. The Examiner had indicated in the telephone interview of 19 November 1996 that such an amendment would be accepted. The amendment was entered,

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and Group II now comprises claims 1-16. Claim 1 continues to be examined to the extent that it reads on the elected invention, a method for transforming cotton plants.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12, and dependent claims 2-11 and 13-16, are indefinite in their recitation of "cotton initiation media" which is confusing, as the explants are already from cotton. If a cotton callus initiation medium was intended, amendment of the claims to insert --callus-- before "initiation" would overcome this rejection.

Claim 1 is indefinite in its recitation of "which is not cultivated on cotton initiation media supplied with exogenous plant hormones". The phrase fails to clearly set forth the culture conditions, as it merely states that the explant is not cultured on one type of medium, but fails to indicate whether the explant is cultured at all in any way. Amendment of claim 1 to delete "not" in line 3 and insert --not-- before "supplied" in line 4 would obviate this rejection.

Claims 1-2, 4-13 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for transforming cotton plants comprising transforming dark-grown excised seedling hypocotyls and culturing

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on hormone-free callus initiation medium, does not reasonably provide enablement for a method for transforming cotton plants comprising transforming any cotton explant and culturing on a hormone-free callus initiation medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides no guidance regarding the obtention of embryogenic callus from a multitude of non-exemplified explants from non-exemplified ages of cotton plants cultured on hormone-free callus initiation medium. Instead, embryogenic callus was only demonstrated following the culture of excised hypocotyls which were obtained from dark-grown seedlings, wherein the use of other tissues such as the apical meristem or other plant growth conditions inhibited embryogenic callus formation on hormone-free medium (see, e.g., page 12 of the specification, lines 8-27).

Cotton has traditionally been recalcitrant to tissue culture and somatic embryogenesis, exhibiting a low frequency of embryogenesis and a prolonged culture duration, and a limited range of regenerable genotypes (see, e.g., page 1 of the specification, lines 13-18; page 2, lines 25-27; page 3, lines 1-5). Furthermore, choice of explant type may inhibit the ability of cultured cotton explants to develop into embryogenic callus (see, e.g., Finer et al. [1984], page 41, column 1, bottom

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paragraph, first and second sentences, column 2, first full paragraph, last sentence; page 42, column 1, second full paragraph; and Smith et al., page 330, column 2, bottom paragraph, page 332, column 2, bottom paragraph). Finally, the culture of seedling hypocotyls obtained from plants not grown in the dark resulted in the lack of embryogenic callus formation on hormone-free callus initiation medium (see, e.g., Voo et al. [1991], page 117, column 2, second full paragraph; page 118, Table 1, top row).

Given the unpredictability inherent in the process, the breadth of the claims, and the lack of guidance in the specification as discussed supra, undue experimentation would have been required by one skilled in the art to evaluate the ability of a multitude of non-exemplified cotton explants to produce embryogenic callus on hormone-free callus initiation medium, capable of being regenerated into whole plants.

Claims 1-16 are deemed free of the prior art, given the unpredictability inherent in the process as discussed supra and the failure of prior workers to attempt or obtain embryogenic cotton callus following explant culture on hormone-free callus initiation medium.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

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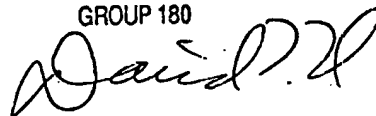
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Robinson, can be reached on (703) 308-2897. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

3 January 1997

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180

A handwritten signature in cursive script, appearing to read "David T. Fox", is written over the typed name and title.